

Attorney's Docket No.: 17108-005001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Partha S. Banerjee et al. Art Unit : 1617
Serial No. : 09/887,496 Examiner : Shaojia A. Jiang
Filed : June 22, 2001
Title : FORMOTEROL/STEROID BRONCHODILATING COMPOSITIONS AND
METHODS OF USE THEREOF

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 C.F.R. 1.132

I, PARTHA BANERJEE, declare as follows:

- 1) I am a co-inventor of the above-identified U.S. Patent Application Serial No. 09/887,496.
- 2) I received a Ph.D. in Pharmaceutics from University of Cincinnati. I have about 15 years of industrial experience in pharmaceutical development. I have been employed at Dey, L.P. since 1999, currently as a Senior Principal Scientist.
- 3) I and my co-workers have tested the stability of formoterol fumarate in water.
- 4) Provided below is data demonstrating the instability of formoterol fumarate in water.

RESULTS

Solutions of formoterol fumarate in purified water were prepared and stored under the conditions shown in the Table below. Stability of formoterol fumarate in solution was measured by standard high performance liquid chromatography (HPLC) techniques. Results are set forth in the Table below.

TABLE

Storage Conditions		Amount of Formoterol remaining as % of initial
5 °C	6 months	91
Room Temperature	6 months	80
60 °C	4 weeks	56

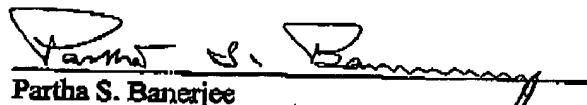
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Method for assay of formoterol solutions in purified water

The solutions prepared in the above Table were placed in scintillation vials with Teflon-lined caps and stored as indicated. At the indicated time points, aliquots of the samples were removed from the scintillation vials. The formoterol concentrations of the samples were analyzed by high performance liquid chromatography.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Date: September 24, 2004
Partha S. Banerjee